REMARKS

I. Claim Status

Claims 1-6 and 8 are currently pending. Claims 3-6 remain withdrawn as being directed to non-elected subject matter, and claim 27 was previously cancelled. Claim 1 is amended to recite "a selective alpha2-adrenoceptor antagonist." Support for this amendment can be found, for example, at page 2 of the specification. New claim 8 has been added herein and is supported in the specification at, for example, page 2. Accordingly, no new matter is added.

Applicants respectfully request that the non-elected subject matter be considered for rejoinder. If the elected claims are found to be allowable, Applicants respectfully request the Office to withdraw the Species Election Requirement between the allowable elected invention and the non-elected inventions and proceed to examine the non-elected claims on the merits. (M.P.E.P. § 821.04).

II. 35 U.S.C. § 112, First Paragraph Rejection

The Office rejected claims 1 and 2 under 35 U.S.C. § 112, first paragraph, as allegedly failing the enablement requirement. (Office Action at 3). Citing the *Wands* factors, the Office alleges that "the specification, while being enabling for the a method for inhibiting the development of severe epilepsy in patients at risk of developing epilepsy due to head trauma, brain ischemia, infection or neurosurgical operation with the selective α_2-adrenoreceptors antagonist atipamezole, does not reasonably provide enablement for the method of inhibiting the development of epilepsy in patients at risk of developing epilepsy with any α_2-adrenoreceptors antagonist." (Office Action at 3).

As an initial matter, Applicants question the rejection of claim 2 for lack of enablement, considering the Office explicitly stated that the specification is enabled for "a method for inhibiting the development of severe epilepsy in patients at risk of developing epilepsy due to head trauma, brain ischemia, infection or neurosurgical operation with the selective α_2-adrenoreceptors antagonist atipamezole," which is recited in claim 2. Clarification on the record for the rejection over claim 2 is therefore respectfully requested.

With respect to claim 1, Applicants respectfully disagree with and traverse this rejection. However, claim 1 has been amended to recite that the α_2-adrenoreceptors antagonist are selective. To the extent that the Office may consider rejecting claim 1 based on the rejection of record, Applicants respectfully disagree and traverse the rejection for the reason that the specification provides enablement for methods for inhibiting the development of severe epilepsy in patients at risk of developing epilepsy due to head trauma, brain ischemia, infection or neurosurgical operation with selective α_2-adrenoreceptors antagonists.

Under the enablement requirement, the disclosure of an Application must be sufficient to inform those skilled in the art how to both make and use the claimed invention. M.P.E.P. § 2164. The working examples from the instant application show how to prepare suitable dosage forms as well as how to use such formulations for treatment. Examples 1 and 2 show that none of the animals in the diazepam/atipamezole group developed severe epilepsy, indicating a clear modifying effect on the development of epilepsy after the beginning of status epilepticus. (*See* Specification at pages 3-7). Thus, Applicants' examples are predictive of *in vivo*

therapeutic activity and one skilled in the art would have expected that selective α_2-adrenoreceptors antagonists could be used to treat a human patient at risk of developing epilepsy, wherein said risk of developing epilepsy is caused by head trauma, brain ischemia, infection, or neurosurgical operation, as claimed. As such, the instant disclosure clearly provides a sufficient degree of guidance and direction to enable one of ordinary skill in the art to make and use the claimed invention. Moreover, "a single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled." (MPEP 2164.02). Accordingly, Applicants respectfully submit that claims 1-2 are enabled.

III. 35 U.S.C. § 103(a) Rejection

The Office rejected claims 1 and 2 under 35 U.S.C. § 103(a) as allegedly unpatentable over Pitkanen et al., *Epilepsia* (2003) 44(Suppl. 9):261-62 ("Pitkanen"), in view of Puurunen, K. et al., *Neuropharmacology* (2001) 40:597-606 ("Puurunen") and Ginsberg et al., *Stroke* (1989) 20:1627-42 ("Ginsberg"). (Office Action at 6.) Applicants traverse this rejection.

The Office has not established a *prima facie* case of obviousness for at least the reason that Pitkanen is not prior art to the present application. Pitkanen was published in October 2003 (see enclosed pages from *Epilepsia*'s website), and the present application claims priority to a U.S. Provisional Patent Application No. 60/461,413 filed on April 10, 2003.

Furthermore, Applicants have previously explained why Puurunen does not establish a *prima facie* case of obviousness. (Amendment and Response dated August 12, 2009 at 5.)

Because Ginsberg does not cure the deficiencies of Pitkanen or Puurunen, no *prima facie* case of obviousness has been established, and this rejection should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Enclosure: Pages from *Epilepsia* website (http://onlinelibrary.wiley.com /journal/10.1111/(ISSN)1528-1167/issues, last accessed on September 22, 2010.)